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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,818	03/18/2004	Ellen G. McMahon	PHA 4231.1 (3650/00)	7016

321 7590 10/10/2007

SENNIGER POWERS
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
10/10/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

Office Action Summary	Application No.	Applicant(s)	
	10/803,818	MCMAHON ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-73* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 12-18 and 5, drawn to a method of treating a cardiovascular disease by employing aldosterone receptor antagonist and an endothelin receptor antagonist, classified in class 514, subclass 1+.

II. Claims 1-4, 12-18 and 6, drawn to a method of treating renal dysfunction disease by employing aldosterone receptor antagonist and an endothelin receptor antagonist, classified in class 514, subclass 1+.

III. Claims 1-4, 12-18 and 7, drawn to a method of treating a liver disease by employing aldosterone receptor antagonist and an endothelin receptor antagonist, classified in class 514, subclass 1+.

IV. Claims 1-4, 12-18 and 8, drawn to a method of treating a cerebrovascular disease by employing aldosterone receptor antagonist and an endothelin receptor antagonist, classified in class 514, subclass 1+.

V. Claims 1-4, 12-18 and 9, drawn to a method of treating a vascular disease by employing aldosterone receptor antagonist and an endothelin receptor antagonist, classified in class 514, subclass 1+.

VI. Claims 1-4, 12-18 and 10, drawn to a method of treating insulinopathy by employing aldosterone receptor antagonist and an endothelin receptor antagonist, classified in class 514, subclass 1+.

VII. Claims 1-4, 12-18 and 11, drawn to a method of treating an edema by employing aldosterone receptor antagonist and an endothelin receptor antagonist, classified in class 514, subclass 1+.

VIII. Claims 19-26, drawn to a method of treating a disease by employing aldosterone receptor antagonist and an endothelin receptor antagonist and an ECE inhibitor, classified in class 514, subclass 1+.

IX. Claims 27-28, 47-73, drawn to a composition comprising aldosterone receptor antagonist and an endothelin receptor antagonist, classified in class 514, subclass 1+ and class 424, subclass 400+.

X. Claims 29-32, 40-46 and 33, drawn to a method of treating a cardiovascular disease by employing aldosterone receptor antagonist and an ECE inhibitor, classified in class 514, subclass 1+.

XI. Claims 29-32, 40-46 and 34, drawn to a method of treating renal dysfunction by employing aldosterone receptor antagonist and an ECE inhibitor, classified in class 514, subclass 1+.

XII. Claims 29-32, 40-46 and 35, drawn to a method of treating a liver disease by employing aldosterone receptor antagonist and an ECE inhibitor, classified in class 514, subclass 1+.

XIII. Claims 29-32, 40-46 and 36, drawn to a method of treating a cerebrovascular disease by employing aldosterone receptor antagonist and an ECE inhibitor, classified in class 514, subclass 1+.

XIV. Claims 29-32, 40-46 and 37, drawn to a method of treating a vascular disease by employing aldosterone receptor antagonist and an ECE inhibitor, classified in class 514, subclass 1+.

XV. Claims 29-32, 40-46 and 38, drawn to a method of treating a insulinopathy by employing aldosterone receptor antagonist and an ECE inhibitor, classified in class 514, subclass 1+.

XVI. Claims 29-32, 40-46 and 39, drawn to a method of treating edema by employing aldosterone receptor antagonist and an ECE inhibitor, classified in class 514, subclass 1+.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VIII are directed to related method of using aldosterone receptor antagonist and an endothelin receptor antagonist. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different functions since they are functioned to treat various diseases. Those diseases are patentably distinct to each other in terms of treatment and etiologies. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions X- XVI are directed to related method of using aldosterone receptor antagonist and an ECE inhibitor. The related inventions are distinct if the (1) the

inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different functions since they are functioned to treat various diseases. Those diseases are patentably distinct to each other in terms of treatment and etiologies. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions XI **and** I-VIII, X-XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the products as claimed can be used in diagnosed process which is materially different from the method of treating diseases.

This application contains claims directed to patentably distinct species of the claimed invention. The diseases states or conditions recited in these claims are subject to **a restriction requirement**. Upon election of a group that recites specific group of diseases, Applicant must also elect a single disease state or condition for examination. Each disease states or conditions are patentably distinct and unrelated to each other because of the different etiologies, pathophysiologies, and treatment among each other. For example, the etiologies, pathophysiologies, and treatment for liver disease is

different than those of insulinopathy and cerebrovascular diseases. These disease states or conditions are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claims 1-73 are generic to the following disclosed patentably distinct species: 1. various aldosterone antagonist, 2. various endothelin antagonist, and 3. various ECE inhibitors and 4. various additional agents. The species are independent or distinct because they are structurally distinct and dissimilar to each other. Applicant is required under 35 U.S.C. 121 to elect **a single disclosed combination species of the compounds recited**, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Because the above restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See M.P.E.P. Sec. 812.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

San-ming Hui
Primary Examiner
Art Unit 1617